

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed April 27, 2009. Currently, claims 21-35 remain pending. Claims 21-35 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 21, 22, and 24-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Engelson et al. (U.S. Patent No. 5,972,019), hereinafter Engelson, in view of Ginsburg (U.S. Patent No. 5,011,488). After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed previously, and as acknowledged by the Examiner, nowhere does Engelson appear to disclose a “cage assembly including a proximal cage and a distal cage”. As currently amended, the claims clarify that the proximal and distal cages are connected. Furthermore, nowhere does Engelson appear to disclose an actuator element “wherein when the actuator element is in the first position, the cage assembly is in the first deployment shape and when the actuator element is in the second position, the cage assembly is in the second expanded shape”, as discussed earlier. As claimed, the actuator element must change the shape of both the proximal and distal cages in transitioning from the first deployment configuration to the expanded configuration such that “both the proximal cage and the distal cage are in an expanded configuration” in the second expanded shape”. Absent a first and second cage, the actuator of Engelson does not appear to be capable teaching actuation of two cages by an actuation element. In the Response to Arguments, the Examiner reiterates that “Engelson does not disclose a proximal and distal cage assembly and asserts that Ginsburg teaches the use of “two elements to remove thrombic material”. The elements appear to be expandable tip (30) on inner flexible tube (14) and expandable body (16) which may

comprise an inflatable balloon (70) on outer flexible tube (18). As depicted and as described neither of the cited expandable tip (30) or expandable body (16) appear to teach a proximal and a distal “cage”. NOUN: An enclosing openwork structure; A skeletal support, as for a building; a framework. (The American Heritage® Dictionary of the English Language: Fourth Edition, emphasis added.) Thus Engelson has been acknowledged on the record to not disclose a cage assembly having a proximal cage and a distal cage and Ginsburg does not appear to overcome the acknowledged deficiency by disclosing a cage assembly including connected proximal and distal cages.

The Examiner has asserted that Ginsburg teaches proximal and distal “elements” and that this suffices to teach proximal and distal cages. Applicants respectfully disagree. Proximal and distal ends of a guidewire are also proximal and distal “elements” and would not suggest a structural equivalence to cages to one of ordinary skill in the art merely by being elements of the guidewire. Further, the expandable tip (30) appears to be constructed as a continuous conical polymeric funnel supported by spring elements (32):

The inner tube 14 may be formed by conventional polymer fabrication procedures. For example, an elongate tubular member may be first formed by extrusion of a suitable thermoplastic. The distal tip may then be expanded by heating and subsequent shrink cooling on a mandrel having the desired geometry, i.e., a conical geometry as illustrated in FIGS. 1 and 2A-2C. The spring elements 32 may then be introduced to the distal tip, either integrally or by attaching to the inner surface thereof. The inner tube will then be a single continuous member from the proximate to distal ends. Usually, the thickness of the wall will be less at the expandable tip in order to provide a desired flexibility. (Col. 5, lines 31-43)

Similarly, inflatable balloon (70) on third flexible tube (18) appears to be formed as a polymeric sheet. Neither device appears to provide an openwork structure and their function, containing thrombic material between two disconnected sheets moved independently of each other by inner tube (14) and third flexible tube (18), would appear to be incompatible with connected cage-like structures and does not appear to teach an actuator element which moves both connected proximal and distal cages of a cage assembly between a first deployment shape and a second expanded shape. Although the Examiner asserts that motivation for the proposed combination would be “to have a less

extensive procedure” it is unclear in what manner a procedure involving the three nested and independently moving tubes (12,14,18) and separate actuators for inflatable balloon (70) and expandable tip (30) would be considered to be “less extensive” by one of ordinary skill in the art. The dictionary definition of “extensive” is: ADJECTIVE: 1. Large in extent, range, or amount. 2. Of or relating to the cultivation of vast areas of land with a minimum of labor or expense. (op.cit.) Neither definition appears to apply in this context. Further, the Examiner asserts that “Ginsburg teaches the use of two cages the proximal and distal cages would be expanded by the same actuator element as shown above”. As discussed, Ginsburg does not appear to disclose two cages, much less two connected cages. The independently advanced and inflated (actuated) balloon (70) at the distal end of moving tube (18) appears to be actuated by a different mechanism, and thus by a different actuator, than expandable tip (30) which appears to advance independently at the distal end of tube (14) and to expand under the influence of attached spring elements (32). Applicants are unable to identify two cages in Ginsburg or a common actuator for either the apparently nonexistent proximal and distal cages or for the separate, and separately actuated, balloon and expandable tip in the discussion provided by the Examiner. Additionally, given the distinctly different operating principles of Engelson and Ginsburg, it would appear that the proposed modification in question would necessarily impermissibly alter the operating principle of Engelson and/or of Ginsburg by replacing a single open cage-like structure with two occlusive membranes having separate actuators. (MPEP 2143.01, Part VI.) The replacement of the cage of Engelson by the membranes of Ginsburg would also appear to render the cage of Engelson unsatisfactory for its intended purpose. (MPEP 2143.01, Part V.)

In the absence of a disclosed or otherwise taught cage assembly including a connected proximal cage and a distal cage with a single actuator for both cages of the cage assembly as found in independent claims 21 and 26, Engelson, Ginsburg, or a combination thereof does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness. Further, the Examiner’s assertion that the motivation for one of ordinary skill in the art to combine the references, that the combination would provide “a less extensive procedure” does not appear to have support given the lack of a clear meaning which might be attributed to the term in this context.

Therefore, for at least this reason, Applicant respectfully asserts that there is no motivation to combine the teachings of Engelson and Ginsburg. Applicants respectfully request that the rejection of nonobvious claims 21 and 26 be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claims 22, 24, 25, and 27-31, which depend from nonobvious claims 21 and 26 respectively, are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

Claims 21-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schmaltz et al. (U.S. Patent No. 5,449,372), hereinafter Schmaltz, in view of Ginsburg. After careful review, Applicant must respectfully traverse this rejection.

As in the rejection over Engelson in view of Ginsburg discussed in detail above, the Examiner readily acknowledges that Schmaltz does not disclose “a cage assembly including a proximal and distal cage”. Ginsburg is again said to teach proximal and distal elements; however the elements in question are neither cages nor connected nor actuated by a single actuator or even by a single actuation mechanism.

The Examiner has also asserted that “Furthermore, since Ginsburg teaches the use of two cages it is inherent that the proximal and distal cages would be able to be expanded by the same actuator element as shown.” First, it must be noted that Ginsburg does not appear to teach the use of two cages, but rather appears to teach two independently moveable funnel-shaped membranes, one of which is said to be a balloon and one of which appears to be a funnel shaped membrane. The three moveable (elements) of Ginsburg do not appear to be operably coupled and so would not appear to share a common actuation element, particularly since they do not appear to share a common actuation mechanism. Second, [T]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To

establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. (MPEP 2112, Part IV.) (Emphasis in the original and added.) Ginsburg does not appear to describe a common actuator for both the balloon and the expandable tip and the balloon.

In the absence of a disclosed or otherwise taught cage assembly including a connected proximal cage and a distal cage with a single actuator for both cages of the cage assembly as found in independent claims 21 and 26, Schmaltz, Ginsburg, or a combination thereof does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness. Applicants respectfully request that the rejection of nonobvious claims 21 and 26 be withdrawn.

Further, claims 22-25 and 27-31, which depend from nonobvious claims 21 and 26 respectively, are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

Claims 32-35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Engelson in view of Ginsburg as applied to claim 21 and further in view of Lefebvre (U.S. Patent No. 5,421,832). After careful review, Applicant must respectfully traverse this rejection.

Initially it should be noted that claims 34 and 35 depend from claim 26 and not from claim 21. Based upon the assumption that the Examiner intended to reject claims 34 and 35 over Engelson in view of Ginsburg as applied to claim 26 and further in view of Lefebvre, the discussions will be combined because the issues are similar. If this was not the Examiner’s intent, an indication that claims 34 and 35 are allowable if rewritten in independent form is anticipated.

As discussed in detail above, claims 21 and 26 are believed nonobvious over Engelson in view of Ginsburg. The single loops of the filter of Lefebvre do not appear to overcome the deficiencies of the combination of Engelson in view of Ginsburg as applied to nonobvious independent claims 21 and 26. Further, the disclosure of Lefebvre does not appear to teach that the flexible bands (6) form a plurality of petal shaped wires

having a distal rake. As depicted in Fig. 2, the bands of Lefebvre appear to be disposed symmetrically about line D and do not appear to have a distal rake, tilt, or the like.

For these and other reasons claims 32-35, which depend from nonobvious claims 21 and 26 respectively, are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

In the Response to Arguments, in addition to the issues discussed above, the Examiner has asserted that it would have been obvious to construct the assembly of Engelson having a plurality of cages (210) since it has been held that mere duplication of the essential working parts of a device involves only routine skill.

The Examiner's attention is drawn to fact that the two cages of the pending claims have separate functions within the embolism treatment device. The proximal cage displaces the embolism and the distal cage provides a filter to catch and retain any thrombus fragments. Accordingly, the mere duplication of a filter of Engelson would appear to result in a device with two filtering sections, but lacking an embolism displacing function and such a dual filter device would not appear to teach a device capable of displacing and filtering emboli.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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